

## Sepsis Study: Same Survival Rate Regardless of Treatment Method



Comparing three treatment methods shows same survival rate

According to a five-year clinical study named ProCESS, for Protocolised Care for Early Septic Shock, and published online on March 18, 2014, in the *New England Journal of Medicine*, the survival rate for patients with septic shock was the same regardless of whether they received treatment based on specific protocols or the usual high-level standard of care.

Led by Derek C. Angus, MD, MPH, and Donald M. Yealy, MD, of the University of Pittsburgh, the large-scale randomised trial included over 1,300 patients from 31 academic hospital emergency departments across the US, and was funded by the National Institute of General Medical Sciences (NIGMS), a component of the National Institutes of Health.

Sarah Dunsmore, PhD, who managed the ProCESS trial for NIGMS, explained the aim was to ascertain whether a specific protocol would increase the survival rates of people with septic shock, and according to her, the findings showed no differences in the patient survival rates, whatever the method of care used. This indicated that sepsis patients in these three treatment groups were receiving effective care in these clinical settings.

As a body-wide inflammation, Sepsis remains hard to predict, identify, diagnose and treat, since it is usually triggered by an infection and can lead to a dangerous drop in blood pressure, called septic shock. This condition starves tissues of oxygen and chokes out the major organs.

Statistics compiled by the Centers for Disease Control and Prevention show sepsis to be the ninth leading cause of disease-related deaths, affecting over 800,000 Americans annually. Listed by the Agency for Healthcare Research and Quality as the most expensive condition treated in US hospitals, sepsis cost more than \$20 billion in 2011.

The aim of the ProCESS trial was to test three approaches to sepsis care. The study participants were randomly divided into these groups:

### Group 1: Early Goal-Directed Therapy

A central venous catheter inserted close to a patient's heart continuously monitored blood oxygen levels and blood pressure. Using intravenous fluids, cardiovascular drugs and blood transfusions, doctors kept these levels within tightly specified ranges using during the first six hours of care. This protocol was based on a 2001 study in an urban emergency department that noted a striking increase in sepsis survival using this approach.

### Group 2: Protocolised Standard Care

Using standard bedside measures like blood pressure via an arm cuff, heart rate and clinical judgment, doctors used this less invasive alternative to evaluate patient status and guide treatment decisions. Here too, patient blood pressure and fluid levels were kept within specified ranges for the first six hours of care.

### Group 3: Standard Care

The doctors in this group did not follow specific guidelines or protocols associated with the study, and patients were treated with the same high level of care they would typically receive in an academic hospital emergency department.

Following the use of an array of statistical analysis tools, the ProCESS investigators were able to conclude that the three treatment arms produced results that were essentially indistinguishable for a range of patient outcomes such as survival at 60 days, 90 days and one year; heart and lung function; length of hospital stay; and a standardised measurement of health status at discharge.

Yealy described the ProCESS trial as being key in the resolution of a long-standing clinical debate regarding the most efficient treatment method for sepsis, especially during the critical first few hours of treatment. For Angus the study clarified that, as long as sepsis was recognised swiftly and patients treated adequately with fluid and antibiotics, there was no mandated need for more invasive care in these patients.

According to Dunsmore, ProCESS was a milestone as the first large-scale clinical trial to be supported by NIGMS, which primarily funds basic, non-disease-targeted research. It was now hoped that ProCESS and other NIGMS- and NIH-funded sepsis research efforts will help improve treatment, speed recovery and increase survival rates for sepsis patients.

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